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(54) Radiopaque stent markers.

(57) A radiopaque marker associated with a stent which is adapted to be implanted into a body lumen of a patient to maintain the patency thereof and a convenient and accurate method for affixing the radiopaque marker to the stent. The radiopaque marker defining an acceptable profile and capable of facilitating, under fluoroscopy, the identification of the position, diameter and length of a stent without obscuring the lesion being repaired and without impeding the deformation of an expandable stent.

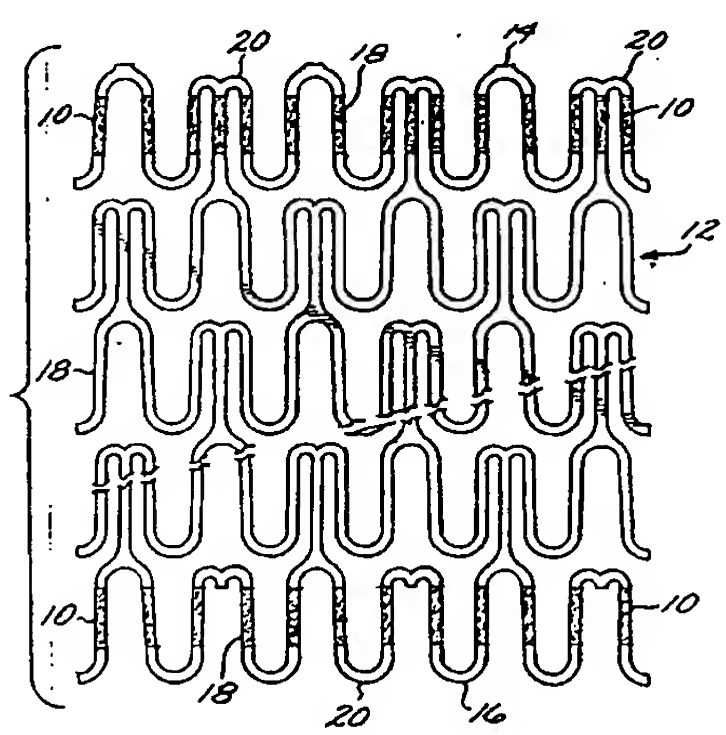

FIG. 1A

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BACKGROUND OF THE INVENTION

This invention relates to endoprosthesis devices, generally called stents, and, more particularly, radiopaque markers for use with endoprosthesis devices.

Stents are useful in the treatment of atherosclerotic stenoses in blood vessels and are generally tubular shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. They are particularly suitable for use in supporting and holding back a dissected arterial lining which can occlude the fluid passage way therethrough.

In order to accomplish precise placement of stents, various means are employed to identify the position of the stent within a blood vessel. One means frequently described for accomplishing precise placement of a stent is the attachment of radiopaque markers to the stent so that through the use of fluoroscopy, the position of the stent within a blood vessel can be identified. Once the stent with its radiopaque markers has been implanted, subsequent checkups of the treated segment are easily performed since the markers remain visible under fluoroscopy.

Conventional radiopaque markers, however, have various limitations. Upon attachment to a stent, certain conventional radiopaque markers define a profile that is readily discernible from that of the stent, thereby comprising projections which may undesirably alter the contemplated profile of the stent. That is, these conventional radiopaque markers protrude from the walls of the stent and depending upon their location upon the stent, may either project into the blood flow or into the walls of the blood vessel. In addition, these conventional radiopaque markers are limited in that their attachment to the stent can be tedious and imprecise.

Other conventional radiopaque markers restrict the expansion capabilities of an expandable stent by adding rigidity to the stent in areas designated for stent deformation. Still other conventional stents utilize material, such as tantalum, that is effective for use in identifying the location of a stent within a vessel, but fluoroscopically illuminate so brightly so as to obscure proper visibility of the blood vessel lesion, thereby impairing the ability to repair the lesion. Finally, conventional radiopaque markers do not generally, under fluoroscopy, provide the operator with means to accurately assess stent length and diameter.

To overcome the problems and limitations associated with stents having conventional radiopaque markers, it would be desirable to employ radiopaque markers that can be consistently and precisely attached to a stent, that do not limit the expansion capabilities of an expandable stent, that define an acceptable profile, that provide means to assess stent length and diameter and that do not obscure the blood vessel lesion being repaired.

SUMMARY OF THE INVENTION

Particular embodiments of the invention provide a radiopaque marker that may be consistently and precisely affixed to a stent, that does not limit the expansion capabilities of an expandable stent, that has an acceptable profile and that may effectively identify the position, diameter and length of a stent within a blood vessel without obscuring a lesion being repaired. Certain embodiments also provide means for affixing to a stent a radiopaque marker having the aforementioned characteristics.

A radiopaque marker embodying the invention may be utilized with stents having various geometric shapes and materials. In addition, the radiopaque marker may be positioned anywhere on a stent and may comprise any plateable radiopaque material having various patterns. Further, any acceptable means for affixing the radiopaque marker to a stent may be employed. It is preferable, however, that the means for attaching a radiopaque marker, its location upon a stent as well as the material and geometric shape of the stent, be selected so that a stent incorporating the radiopaque marker embodying the invention may benefit from the advantages provided thereby.

In a preferred embodiment, the radiopaque markers of the present invention are affixed to both a distal and a proximal end of a generally cylindrical stent. In this embodiment, the radiopaque marker material is gold and is affixed to the outside circumference of a generally cylindrical stent by means of plating. Although gold is the designated material of this embodiment, other biocompatible plateable radiopaque materials, such as platinum, are equally desirable. Plating is preferable since it can be performed easily and with accuracy and can be utilized to produce an acceptable radiopaque marker profile. It is contemplated that the thickness of the radiopaque marker material upon a stent be in the range of about 0.008 to 0.080 mm (.0003 to .003 inches) on the exterior surface of the stent, and if required for fluoroscopic illumination, the same thickness can be plated to the inner stent surface. It is also contemplated that the stent may comprise any material, for example any metal or plastic, upon which gold may be plated.

Although radiopaque material may be plated on only a portion of the circumference of the stent, in a preferred embodiment it is contemplated that the entire circumference of the stent be plated, thereby producing a stent with a band of radiopaque material at its distal and proximal ends. Moreover, it is significant that only the ends of the stent are plated and that gold, or a similarly effective material, may be selected as the plating material. Plating provides controlled deposition of the radiopaque material on the stent thereby controlling its fluoroscopic illumination. By plating only the two ends of the stent, the fluoroscopic illumination is thus limited to the ends of the stent. These

two features minimize the possibility of obscuring the fluoroscopic visualization of the blood vessel being treated.

In addition, by plating with radiopaque material at both ends and upon the outside of a generally cylindrical stent, not only can the location of the stent be determined under fluoroscopy, but the length and diameter of the device can be determined as well. This is particularly useful where the subject stent is expandable, since the degree of expansion can be ascertained by noting the height of each radiopaque marker and the relative distances between the radiopaque markers. Further, it can be determined under fluoroscopy whether or not the stent is twisted or otherwise improperly seated within a blood vessel.

In order to successfully plate gold, or any acceptable radiopaque marker material upon a stent, the stent is placed upon a mandrel, then is masked and plated. In a preferred procedure, the stent is placed upon an elongated cylindrical mandrel, masked with shrink tubing, portions of which are lased away to expose the areas of the stent desired to be plated and, thereafter, plated with the desired radiopaque material. It is contemplated that the mandrel may comprise annular recesses which function to allow portions of an interior circumference of a stent, as well as the exterior of that stent, to be plated.

Subsequent to the completion of the plating procedure, in a preferred procedure the shrink tubing is detached from the stent and the stent is removed from the mandrel. It is contemplated that the shrink tubing may be cut from the stent utilizing a laser. Alternatively, the shrink tubing may be dissolved with chemicals. It also is contemplated that the shrink tubing be pre-fabricated or cut to size (by means of a laser) to precise dimensions, so that the tubing properly can perform its masking function.

Since a preferred embodiment contemplates gold plating as the avenue for affixing radiopaque markers to a stent, and since gold plating may stiffen a stent in the areas of plating, it is contemplated that expandable stents may be plated in areas where additional rigidity does not affect the expansion capabilities of the stent. Thus, portions of a stent that do not deform upon expansion are plated with gold or the desired radiopaque material. In this way, the stent can freely and uniformly expand and elastically deform without additional restrictions, thereby accomplishing its expansion function while still benefitting from the advantages of the present invention.

In another embodiment, the entire exterior surface of a stent is plated with radiopaque material. Thereafter, the portions designated to retain radiopaque material are masked and the radiopaque material is etched away from the remaining portions of the stent.

In yet another embodiment, a generally cylindrical stent is fitted with radiopaque markers having some geometrical configuration or placed upon a stent in some pattern. For instance, a radiopaque marker may comprise a sine wave pattern so that under fluoroscopy, the configuration of the stent may be quickly ascertained. That is, it can be readily ascertained whether the stent is improperly twisted or contorted and, in the case of an expandable stent, whether the stent properly has been deformed.

Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1A illustrates a partial view of a stent embodying radiopaque markers.

FIG. 1B illustrates a partial view of another stent embodying radiopaque markers.

FIG. 2A illustrates a schematic view of a stent embodying radiopaque markers.

FIG. 2B illustrates a schematic view of another stent embodiment having radiopaque markers.

FIG. 3A illustrates a perspective view of a mandrel having annular recesses.

FIG. 3B illustrates a perspective view of a mandrel without annular recesses.

FIG. 4A illustrates a partial cross-sectional view of a masked stent loaded upon a mandrel having annular recesses.

FIG. 4B illustrates a partial cross-sectional view of a masked stent loaded upon a mandrel without annular recesses.

FIG. 5 illustrates a schematic view of the stent having two rows of radiopaque material along the longitudinal axis in addition to the radiopaque material on either end of the stent.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As is shown in the drawings, which are included for purposes of illustration and not by way of limitation, there is provided a radiopaque marker 10 (FIGS. 1 and 2). Conventional radiopaque markers are limited in that they may comprise undesirable projections extending from a stent, may be arduous to attach, restrict the expansion capabilities of an expandable stent and may be ineffective in the identification of the position, orientation and configuration of a stent. The illustrated radiopaque marker 10 defines an acceptable, very low, profile, conveniently may be affixed to a stent, does not impede the expansion capabilities of an expandable stent, and may be useful in identifying the position, orientation and configuration of a stent within a blood vessel. The illustrated radiopaque marker therefore, provides superior means

of marking a stent.

The illustrated marker facilitates precise placement of a stent 12 by way of its novel configuration, position upon a stent, and material properties. The characteristics of a radiopaque marker 10 are selected to assure that a stent 12 embodying the radiopaque marker 10 may benefit from the advantages which the invention provides. Thus, radiopaque marker 10 may have various geometric shapes, comprise various materials and may be positioned anywhere on a stent 12, so long as the desired advantages of the invention are achieved.

In a preferred embodiment, radiopaque marker 10 is plated upon an outer circumference of a generally cylindrical stent 12 and upon a proximal end 14 and a distal end 16 of the stent 12. In another embodiment, it is contemplated that an inner circumference underlying the outer circumference be plated as well. By utilizing plating as the means for affixing radiopaque marker 10 to a stent 12, a minimum profile may be achieved. It is contemplated that the thickness of radiopaque marker 10 be in the range of about 0.008 to 0.080 mm (.0003 to .003 inches) . As such, the radiopaque marker 10 does not appreciably alter the profile of stent 12 and therefore, does not result in stent 12 having substantial projections extending into the blood flow or into the walls of the blood vessel being repaired.

In addition, by plating or similarly affixing radiopaque material upon a stent, radiopaque markers 10 easily and accurately can be affixed to a stent. That is, plating is an improved means of affixing radiopaque material to stent 12 over conventional means of affixing radiopaque markers, such as sewing or bonding, which can be tedious and imprecise.

Although it is not necessary for all embodiments, the preferred embodiment contemplates that the entire circumference of the stent be plated at both its proximal end 14 and distal end 16. It is also contemplated that the plating material may be gold or a material, such as platinum, which has similar radiopaque characteristics .

It is significant that gold, or a similar material, is contemplated as the preferred radiopaque marker material. Other metals suitable as radiopaque markers include, for example, platinum and silver. By selecting such a material, the stent may be effectively identified under fluoroscopy. In various conventional stents, the radiopaque material employed glows so brightly under fluoroscopy so as to obscure the lesion being repaired. In contrast, the images of radiopaque markers comprised of gold or platinum do not, under fluoroscopy, substantially obscure the lesion being repaired.

It is also significant that the preferred embodiment contemplates affixing radiopaque markers 10 to the ends of stents 12 having various geometric configurations (see FIGS. 2A and 2B). By doing so, the orientation or configuration of the stent 12, irrespective of its geometric configuration, can be ascertained, which is particularly important to the determination of whether a stent has completely repaired a blood vessel. By noting the distance between the radiopaque bands, the length of the stent 12 can be ascertained and compared to an expected stent length. By observing the height or width of the radiopaque markers 10, the extent of expansion of an expandable stent 12 can be ascertained and compared with expected values. Similarly, by examining the radiopaque markers embodying the invention under fluoroscopy, it can be determined whether the stent 12 is twisted or otherwise improperly is seated within a vessel.

The plating of radiopaque markers upon a stent may add some rigidity to a stent in the areas of plating. Since this is the case, the preferred embodiment contemplates affixing radiopaque markers 10 to only those portions of an expandable stent 12 that do not deform upon expansion. As shown in FIGS. 1a and 1b for example, radiopaque markers 10 may be affixed to straight segments 18 of the proximal end 14 and distal end 16 of a stent. Upon expansion, the curved portions 20 of the stent 12 may deform so as to allow the stent 12 to expand, while the straight portions 18 may remain undeformed. By affixing radiopaque markers 10 to the straight portions 18 of stent 12 as shown in FIGS. 1A and 1B, the additional rigidity added to the stent 12 by the radiopaque markers 10 does not impede expansion. Therefore, an expandable stent having radiopaque markers 10 embodying the invention can expand uniformly and predictably.

In order to plate a radiopaque marker 10 upon a stent 12, a mandrel 30 may be employed (see FIG. 3A) . The mandrel 30 may comprise any suitable material formed into an elongate cylindrical shape having a main portion 21 with a cross-sectional diameter sized for receiving stent 12. The mandrel may further embody a collar 22 formed or attached to one end of the mandrel 30 that has a cross-sectional diameter larger than that of stent 12 and two annular recesses 23 formed in the main portion 21 which have cross-sectional diameters less than that of the main portion 21. The collar 22 functions as a stop and may aid in registering stent 12 upon the mandrel 30. Annular recesses 23 function to allow interior surfaces of stent 12 to be plated. In another embodiment of mandrel 30 (FIG. 3B), recesses 23 may be sufficiently shallow or be missing entirely from mandrel 30 so that, where desirable, interior surfaces of stent 12 are not plated with radiopaque material.

In a preferred method, stent 12 is placed upon mandrel 30 and heat shrink tubing 32 (see FIGS. 4A and 4B) is slipped over stent 12. The heat shrink tubing 32 is then exposed to heat to shrink the tubing on the stent 12. It is contemplated that the heat be concentrated at a midpoint of the heat shrink tubing 32

and then gradually apply heat towards each end so as to prevent distortion of the stent. The shrink tubing 32 may be any polyester having heat shrink properties and the ability to mask the stent during the electroplating process.

Once the heat shrink tubing 32 is snug upon stent 12, the stent may be precisely positioned on the mandrel 30 and then temporarily secured in place using a high temperature wax. Where it is desired to plate an interior as well as an exterior surface of stent 12, the annular recesses 23 may be aligned with the interior portions of the stent 12 desired to be plated (see FIG. 4A). Where it is deemed undesirable to plate the interior surface, no such further alignment is necessary (see FIG. 4B). Next, the curved portions 20 (Fig. 1B) of stent 12 as well as the ends of the mandrel 30 can be dipped in high temperature wax to prevent them from being plated.

In order to plate the desired portions of stent 12, the heat shrink tubing 32 surrounding portions of the stent 12 to be plated may be cut away using a standard CO_2 laser or its equivalent. The laser output is to be limited so that stent 12 and mandrel 30 are not affected. By utilizing a mandrel 30 without annular recesses (see FIGS. 3B and 4B), portions of the heat shrink tubing 32 may be lased away so that only the outer circumferences of stent 12 may be plated. By employing the mandrel 30 illustrated in FIGS. 3A and 4A, portions of the heat shrink tubing 32 overlaying annular recesses 23 may be lased away, thereby resulting in a stent 12 having desired portions of its interior as well as its exterior plated with radiopaque material (see FIG. 2B).

As with any electroplating process, an electrical current is used in the process of putting a metallic coating on a metal or other conducting surface. In the preferred embodiment, a gold solution exists in the form of positively charged ions that have lost one or more electrons. The stent is connected to the cathode or negative terminal and the anode, or positive electric terminal, is connected to the stainless steel mandrel 30 which is dipped into the gold solution. The ions are attracted to the cathode and the coating is deposited on the stent metal surface. As is known in the art, the thickness of the layer deposited depends on the amperage of the electric current, the concentration of the metallic ions and the length of time that the stent is plated. The plating process should be at a low enough amperage to prevent mapping, nodules, or a matte surface.

After plating the gold on the stent, the wax is removed from stent 12 and mandrel 30 by inserting the two elements into acetone or an equivalent solution.

As can be appreciated from the drawings (FIGS. 2A and 2B), the end portions 36,38 of a stent 12 which are not masked, are plated with radiopaque material and the portions of the stent 12 which are masked, are not plated.

Once the stent 12 is plated with a radiopaque marker 10, it is removed from the mandrel 30 and the heat shrink tubing 24 is stripped away. The heat shrink tubing 24 may be removed, for example, by cutting it with a laser or in the alternative, dissolved with chemicals. Finally, the mandrel 30 is withdrawn from the plated stent 12 and the stent 12 may be cleaned with an alcohol-containing solution such as "Alcomox," or equivalent solution.

In another embodiment, the entire exterior surface of a stent may be plated with radiopaque material. Subsequent to plating, the stent 12 is masked and subjected to etching. In this embodiment, the areas designated to retain radiopaque material are masked and the radiopaque material is etched away from the remaining portions of the stent.

In yet another embodiment, radiopaque markers having some pattern are affixed to a generally cylindrical stent so as to facilitate the identification, position and configuration of a stent 12 within a blood vessel. For example, the pattern of a radiopaque marker 10 may be in the form of a sine wave. As the sine wave expands along with the stent during deployment, it is visible under fluoroscopy and it can be determined whether the stent 12 is properly seated within a blood vessel by viewing the amplitude and shape of the sine wave radiopaque marker. As another example, as depicted in Fig. 5, the pattern 13 of a radiopaque marker 10 may be a continuous or dashed line extending from the proximal end 14 to the distal end 16 of stent 12. A longitudinal marker of the type described will allow the doctor to determine if the stent has twisted upon deployment or if it expanded unevenly.

In an alternative embodiment, a radiopaque plastic may be coated or affixed to all or a portion of a stent. In this embodiment, a radiopaque plastic is formed by loading a plastic material with a radiopaque material such as barium sulfate or bismute trioxide. The resultant mixture is then coated or affixed to the stent. Several methods of affixing the radiopaque material to the stent are contemplated and include: (1) melting the radiopaque material and then dipping the stent into the melt; (2) solvent casting; and (3) vacuum deposition. These methods are known generally and various process steps are apparent to those skilled in the art. As with the plating process steps described above, the stent can be masked and mounted on a mandrel and then coated, by dipping, solvent casting, or vacuum deposition.

From the foregoing it will be appreciated that the radiopaque marker described effectively identifies the location and configuration of a stent within a patient's body lumen of a patient and provides a method and apparatus for constructing the same.

While several particular forms of the invention have been illustrated and described, it will also be apparent that various modifications can be made without departing from the scope of the invention. Thus,

it should be understood that various changes in form, and detail, and application of the present invention may be made without departing from the scope of this invention.

Claims

1. A radiopaque marker (10), comprising: a band of radiopaque material affixed by means of plating to at least a portion of an outer circumference of a generally cylindrical stent (12).

2. The radiopaque marker (10) of claim 1, wherein said radiopaque marker is affixed adjacent a proximal end (14) and a distal end (16) of the generally cylindrical stent (12).

3. The radiopaque marker (10) of claim 1, or claim 2 wherein said stent (12) is expandable and comprises a deforming portion (20) and a non-deforming portion (18), the radiopaque marker being affixed to said non-deforming portion (18).

4. The radiopaque marker (10) of any preceding claim, wherein said radiopaque material comprises a metal taken from the group of gold, platinum and silver.

5. The radiopaque marker (10) of any preceding claim, wherein said band of radiopaque material has a thickness in the range of approximately 0.008 to 0.080 mm (.0003 to .003 inches).

6. The radiopaque marker (10) of any preceding claim, wherein said band extends a full circumference of a portion of said stent (12).

7. The radiopaque marker of any preceding claim, wherein said band comprises a pattern (13).

8. The radiopaque marker (10) of claim 7, wherein said pattern (13) comprises a wave-like shape.

9. A medical device for implantation in a blood vessel or artery, comprising:
 an intravascular stent (12) having a generally cylindrical configuration; and
 a radiopaque material (10) affixed to a portion of said intravascular stent so that said radiopaque material (10) is visible under fluoroscopy and can be easily located in the blood vessel or artery where said stent (12) is being implanted.

10. The medical device of claim 9, wherein said intravascular stent (12) has a proximal end (14) and a distal end (16) and said radiopaque material (10) is coated adjacent said proximal end (14) and said distal end (16).

11. The medical device of claim 9, or claim 10 wherein said stent (12) is expandable and comprises a deforming portion (20) and a non-deforming portion (18), and said radiopaque material (10) is affixed to said non-deforming portion (18).

12. The medical device of any of claims 9 to 11, wherein said radiopaque material (10) comprises a metal taken from the group of metals consisting of gold, platinum and silver.

13. The medical device of any of claims 9 to 12, wherein said radiopaque material (10) has a thickness in the range of approximately 0.008 to 0.080 mm (.0003 to .003 inches).

14. The medical device of any of claims 9 to 13, wherein said radiopaque material (10) extends a full circumference of a portion of said stent (12).

15. The medical device of any of claims 9 to 14, wherein said radiopaque material comprises a pattern (13).

16. The medical device of claim 15, wherein said pattern of said radiopaque material comprises a wave-like shape.

17. A method for affixing a radiopaque marker to a generally cylindrical stent (12) comprising the steps:
 placing said stent (12) upon a mandrel (30);
 attaching masking material (32) to a portion of said stent (12);
 coating at least a portion of said stent (12) with a radiopaque material;
 removing said masking material (32) from said stent; and
 removing said stent (12) from said mandrel (30).

18. The method of claim 17, wherein said masking material (32) is a heat shrink tubing, which is heated and applied to a portion of said stent (12).

19. The method of claim 17 or claim 18, wherein said coating step includes plating a coating of metal on a portion of said stent (12), the metal taken from the group gold, platinum and silver.

20. The method of any of claims 17 to 19, wherein said coating step includes coating a radiopaque plastic on a portion of said stent.

21. The method of any of claims 17 to 20, wherein

said coating step includes dipping said stent (12) in a solution of radiopaque plastic so that said portion of said stent receives said coating of radiopaque plastic.

22. The method of any of claims 17 to 21, wherein said coating step includes solvent casting a radiopaque plastic on at least said portion of said stent (12).

23. The method of any of claims 17 to 22, wherein said coating step includes vacuum deposition of a radiopaque plastic on at least said portion of said stent (12).

24. The method of any of claims 17 to 23, wherein said masking material (32) is pre-fabricated to pre-determined dimensions.

25. The method of any of claims 17 to 24, wherein said masking material (32) is cut to desired dimensions once placed upon said stent (12).

26. The method of claim 25, wherein said masking material (32) is cut to desired dimensions by use of a laser.

27. The method of any of claims 17 to 26, wherein said masking material (32) is removed by using a laser to cut said masking material from said stent (12).

28. The method of any of claims 17 to 27, wherein said masking material (32) is removed by dissolving said masking material with chemicals.

29. A method for affixing a radiopaque marker (10) to a generally cylindrical stent (12) comprising the steps:

placing said stent upon a mandrel (30);

plating said stent with a radiopaque material;

masking a portion of said stent with a masking material (32);

etching said radiopaque material from an unmasked portion of said stent; and

removing said masking material from said stent.

30. The method of claim 29, wherein said plating step includes depositing a coating of metal on a portion of said stent, said metal taken from the group gold, platinum and silver.

31. The method of claim 29 or claim 30, wherein said plating step includes depositing a coating of a radiopaque material on a portion of said stent (12).

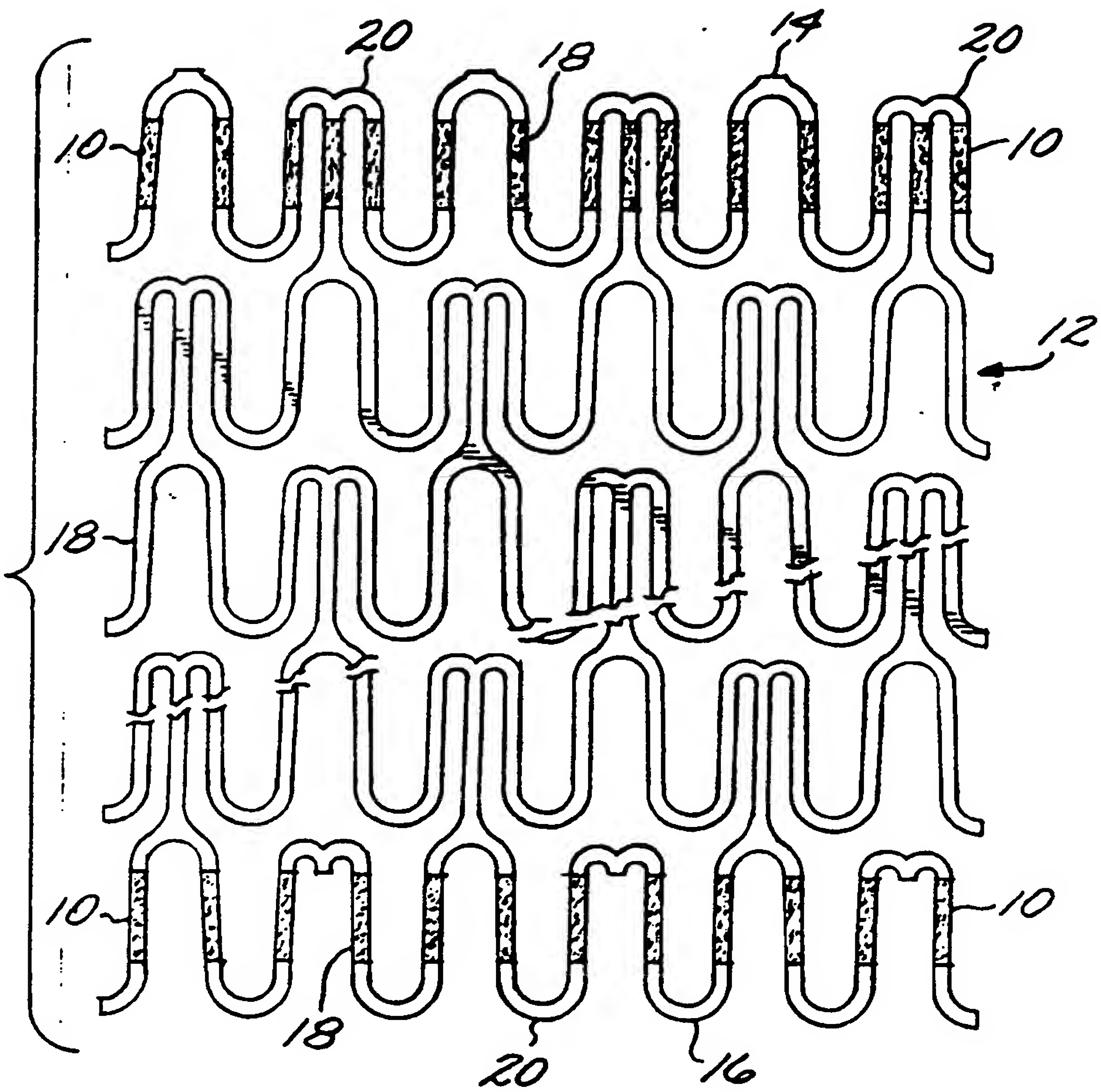

FIG. 1A

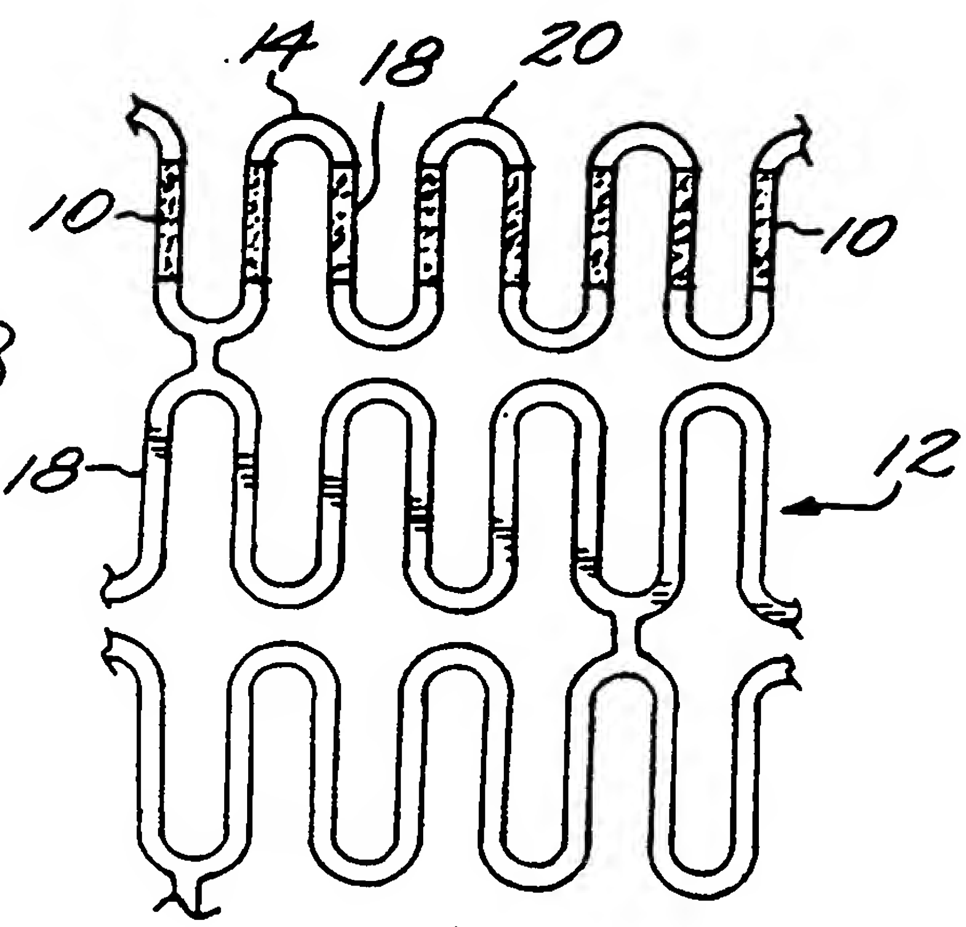

FIG. 1B

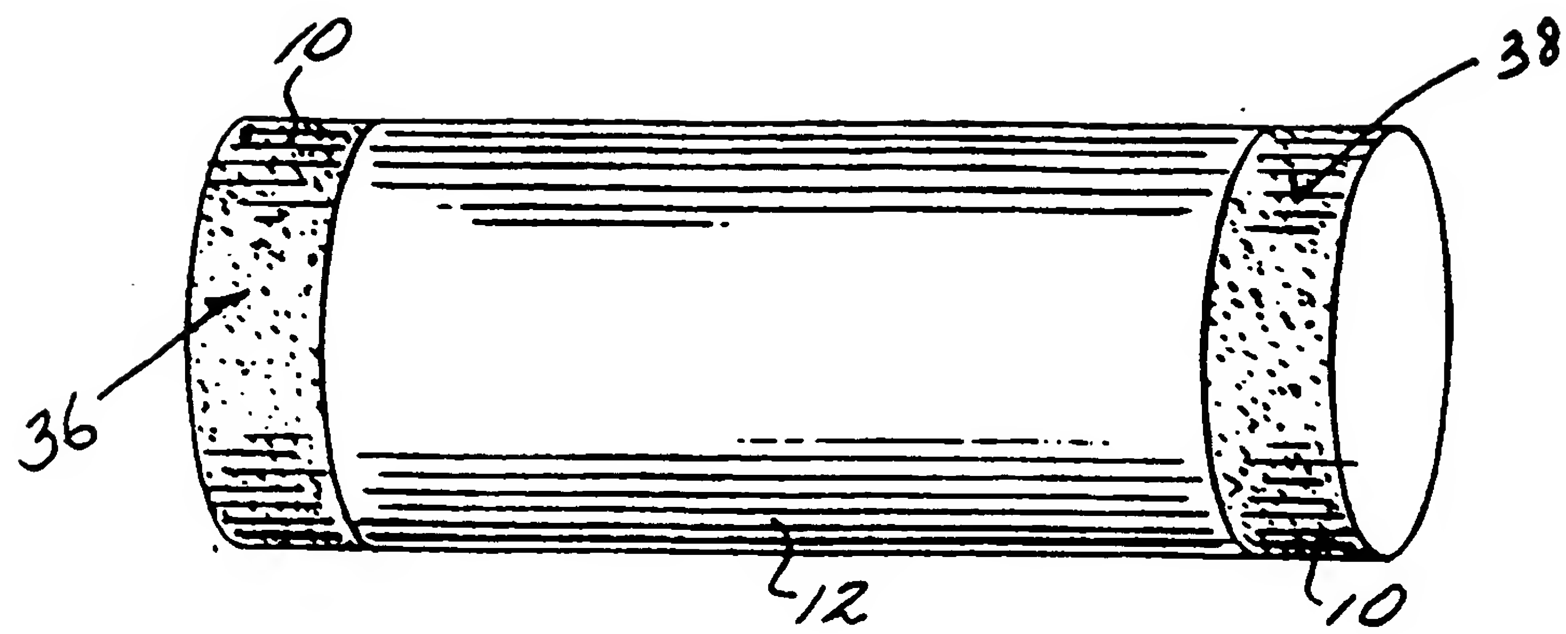

FIG. 2A

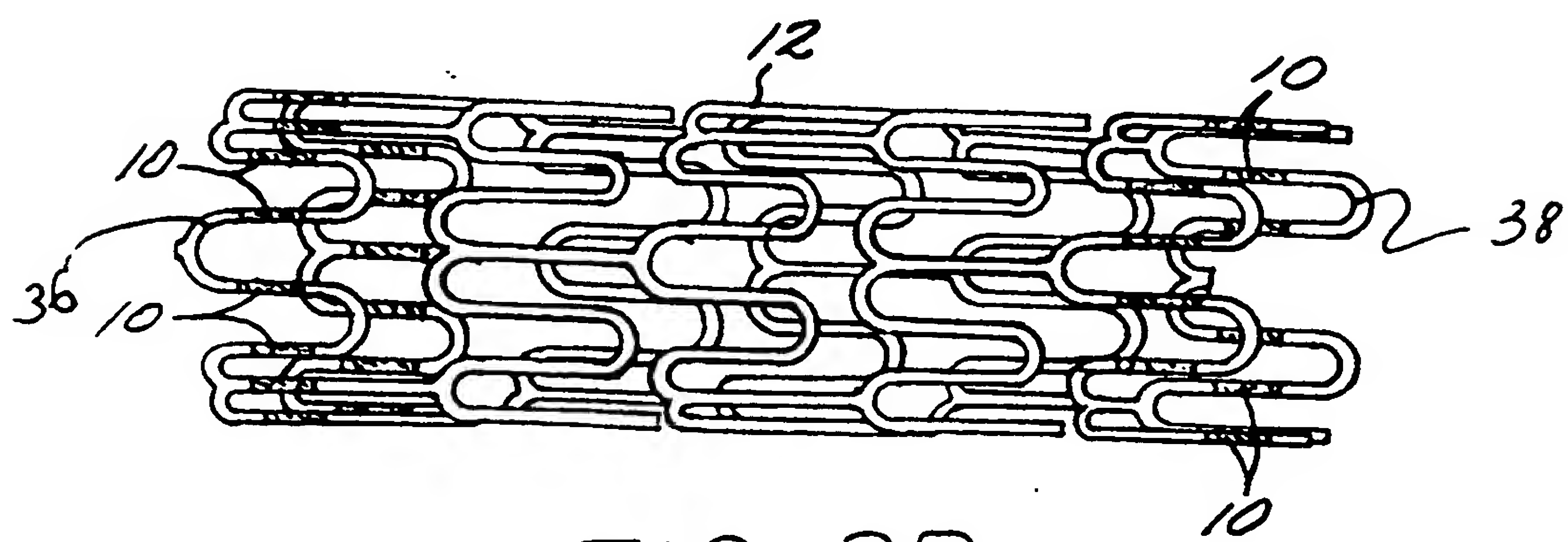

FIG. 2B

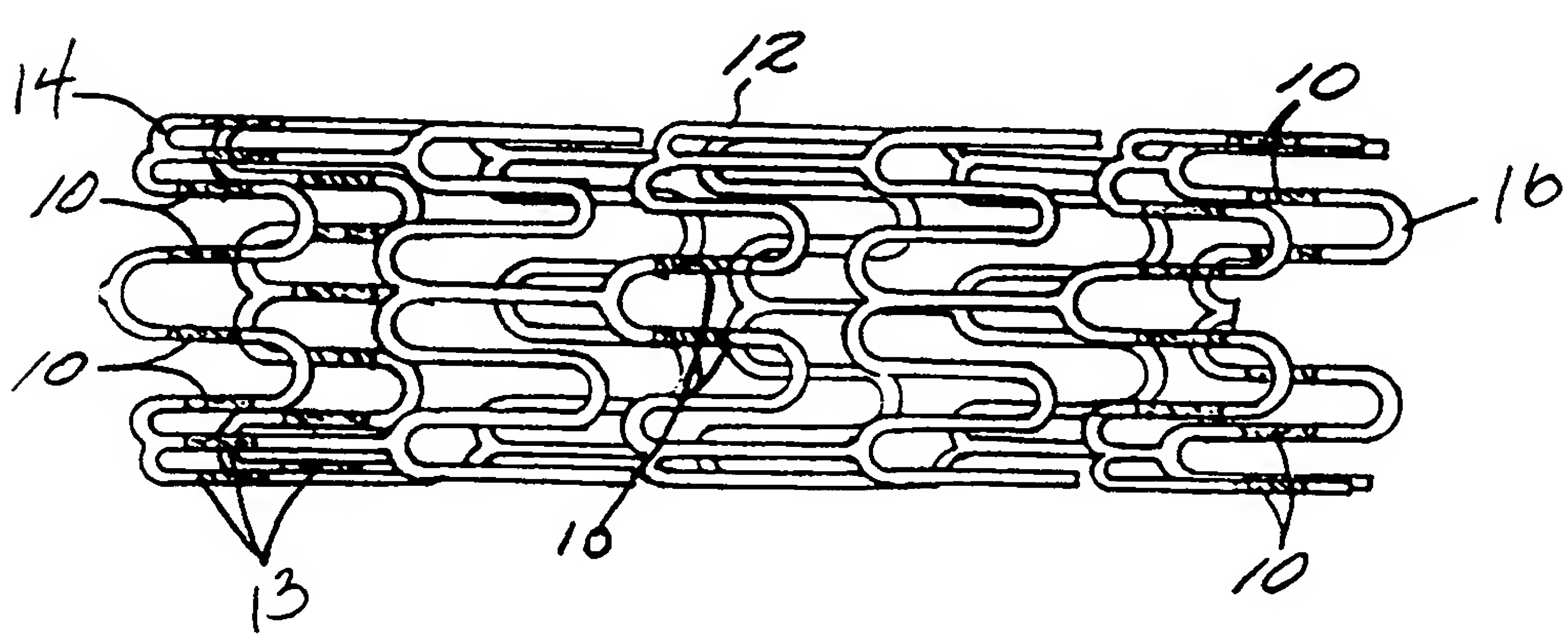

FIG. 5

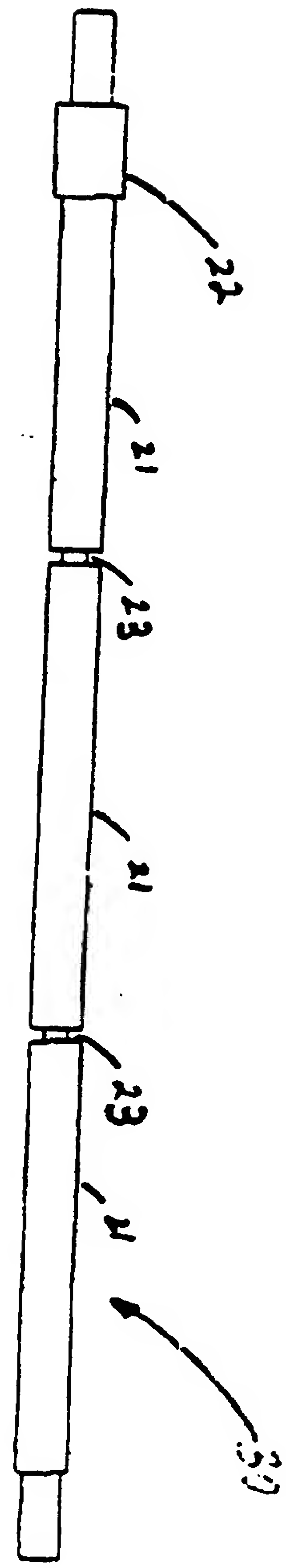

FIG. 3A

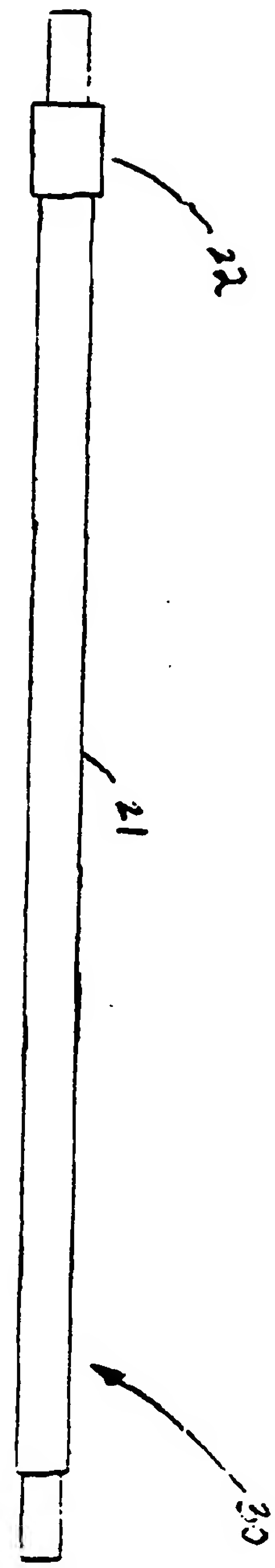

FIG. 3B

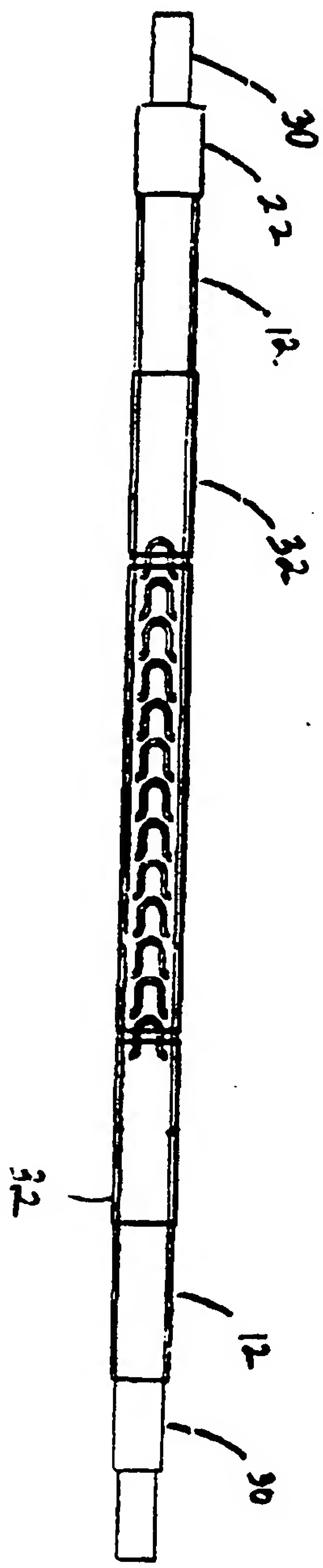

FIG. 4B

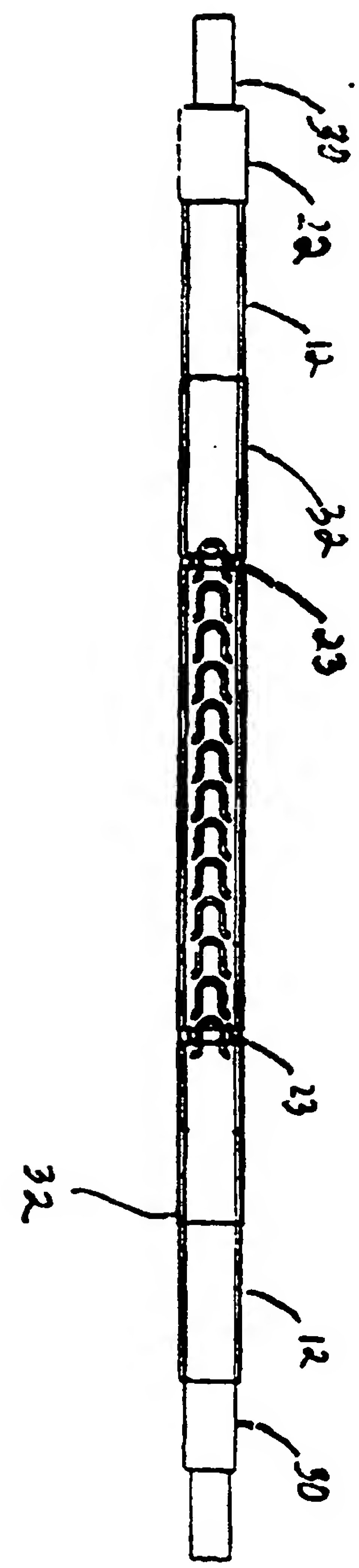

FIG. 4A